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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,743	02/16/2001	Yuichi Murayama	P689a	5528

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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	

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#7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,743	MURAYAMA ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,11-16,18,19,22 and 25-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,11-16,18,19,22,25-33 and 35-50* is/are rejected.

7)☒ Claim(s) *34 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 23, 2003. Claims 1, 7, 8, 11-16, 18, 19, 22, and 25-51 are under consideration. The terminal disclaimer is acknowledged.

Drawings

1. Figure "Prior Art" portions of Figures 1-5F should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicant contends that the Examiner misunderstood the figures. However, the Examiner did not misunderstand the figures. Figures depicting the uncoated coils, would be considered conventional, thus, prior art. Therefore, the coil at the bottom of figure 1 should be labeled as prior art. Thus, the rejection is reiterated.

2. The drawings are objected to because they are dark and unclear. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Response to Arguments

3. Applicant's arguments with respect to claims 1, and 12 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 11-13 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. in US Patent No. 5,733,329.

Regarding claims 1 and 12, Wallace et al. disclose an endovascular apparatus for developing an inflammatory response in a body cavity with cellular manipulation having a separable implant (such as 300, etc.), at least in part of at least one biocompatible and bioabsorbable polymer, as recited in column 4, etc. to cause permanent blockage of flow of blood in the body cavity by inducing the formation of scar tissue therein, wherein an aneurysm device will necessarily block the flow of blood and induce the formation of scar tissue, Further, on page 2, lines 20-22 the current application defines scarring as "wound healing." Thus, when the polymer is inserted it would necessarily include the formation of scar tissue. Moreover, Vacanti et al. disclose an endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity, as discussed throughout the specification.

Regarding claim 11, Wallace et al. disclose that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that promotes cellular

manipulation, controlled inflammatory response and vascular healing, as recited in column 4, where the polymer is capable of controlling the inflammatory response.

Regarding claim 13, Wallace et al. disclose that as applied to claim 12, as well as, an implant with a noncollagenous protein, as recited in column 4.

Regarding claim 35, Wallace et al. disclose that as applied to claim 1, as well as, an implant that is a bioactive coil (300).

Regarding claims 36-39, Wallace et al. disclose that as applied to claim 35, as well as, an inert biocompatible coil that is platinum, as recited in column 4, etc. and to coat the coil with a polymer.

Applicant is reminded that functional language does not carry patentable weight in apparatus claims. Statements that do no define any structure accordingly do not serve to distinguish.

6. Claims 1, 8, 11-16, 19, 22, 25-29, 31-33, 40-46 and 48-50 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by Vacanti et al. in US Patent No. 5,759,830.

Regarding claim 1, Vacanti et al. disclose an endovascular apparatus for developing an inflammatory response in a body cavity with cellular manipulation

having a separable implant, at least in part of at least one biocompatible and bioabsorbable polymer, as recited in column 10, etc. to cause permanent blockage of flow of blood in the body cavity by inducing the formation of scar tissue therein, wherein an aneurysm device will necessarily block the flow of blood and induce the formation of scar tissue, wherein column 6, lines 30-35 clearly recite that the invention can be used with blood vessels and column 3, lines 60-67 discuss aneurysms. Thus, when used in blood vessels for aneurysms, the invention would necessarily cause permanent blockage of the flow of blood. Moreover, the invention would block the flow of blood in numerous of the other disclosed implantation sites. Further, on page 2, lines 20-22 the current application defines scarring as "wound healing." Thus, when the polymer is inserted it would necessarily include the formation of scar tissue. Moreover, Vacanti et al. disclose an endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity, as discussed throughout the specification. Applicant's attention is directed to column 5.

Regarding claims 8 and 19, Vacanti et al. disclose that as applied to claims 1 and 13, as well as, a biocompatible and bioabsorbable protein that is at least one protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, and laminin, as recited in column 10, lines 40-60.

Regarding claim 11, Vacanti et al. disclose that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing, as recited in column 5, for example.

Regarding claim 12, Vacanti et al. disclose causing a blockage of flow of blood in a body cavity by inducing the formation of scar tissue therein by providing a separable implant having a form and in part at least one biocompatible and bioabsorbable polymer; and disposing the implant in the body cavity. See the corresponding rejection for claim 1.

Regarding claim 13, Vacanti et al. disclose that as applied to claim 12, as well as, an implant with a noncollagenous protein, as recited throughout.

Regarding claim 14, Vacanti et al. disclose that as applied to claim 12, as well as, an implant that further is at least in part of a growth factor, a growth factor that is an endothelial growth factor, or a basic fibroblast growth factor, as recited in claim 8.

Regarding claims 15 and 16, Vacanti et al. disclose that as applied to claim 14. Although not explicitly recited growth factors such as endothelial and

basic fibroblast are within the scope of the invention and would be obvious to one with ordinary skill in the art.

Regarding claim 22, Vacanti et al. disclose that as applied to claim 1, as well as a biocompatible and bioabsorbable polymer that does not elicit foreign body reaction, as recited throughout the specification.

Regarding claims 25, 41, and 42, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that has a selected composition to provide a controlled degradation time to thereby control intravascular inflammatory reactions; degrading faster than by implanted metal coils and providing a stronger inflammatory reaction than metal coils, as recited throughout the specification with emphasis in columns 5 and 6. Thus, given that disclosed by Vacanti et al. when used to treat blood vessels as disclosed would necessarily provide a stronger inflammatory reaction than with a metal coil. Moreover, it is noted that the claim does not limit the metal coils to be uncoated. Therefore, it would also depend on what the chosen metal is and if it has a coating on it as well.

Regarding claims 26 and 43, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that

regenerates tissue through the interaction of immunologic cells, as recited throughout the specification with emphasis on columns 5 and 6.

Regarding claims 27 and 44, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis, as recited in columns 5 and 6.

Regarding claims 28 and 45, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would accelerates fibrosis within an aneurysm to more strongly anchor the implant than does metal coils. However, applicant has not positively recited in the claims that this invention is used in an aneurysm. Thus, given that disclosed by Vacanti et al. when used to treat blood vessels as disclosed would necessarily accelerate fibrosis more than with a metal coil. Moreover, it is noted that the claim does not limit the metal coils to be uncoated. Therefore, it would also depend on what the chosen metal is and if it has a coating on it as well.

Regarding claims 29 and 46, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more

resistant to a water hammer effect of pulsatile blood than when treated by metal coils. Again, given the broad nature of what can encompass metal coils, Vacanti et al. accomplish that given that disclosed. There are no structural features provided to distinguish.

Regarding claims 31 and 48, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would necessarily restrict aneurysm recanalization by accelerated scar formation when used in treating blood vessels.

Regarding claims 32 and 49, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that would necessarily induce organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves when used in treating blood vessels.

Regarding claims 33 and 50, Vacanti et al. disclose that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymer that is less thrombogenic than metal coils and would accelerate aneurysm healing with less thrombogenicity.

Regarding claim 40, Vacanti et al. disclose that as applied to claim 12, as well as, disposing an implant at the implant site and gradually absorbing the biocompatible and bioabsorbable polymer without leaving residua in the implantation site. The current application specification does not define residua, so the scope of what is considered residua is not limited.

Applicant is reminded that functional language does not carry patentable weight in apparatus claims. Statements that do no define any structure accordingly do not serve to distinguish.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al. in US Patent No. 5,759,830.

Regarding claims 7 and 18, Vacanti et al. disclose that as applied to claims 1 and 12. However, a biocompatible and bioabsorbable polymer that is at least one polymer selected from the group consisting of poly~glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone have not been explicitly recited. On the other hand, the current disclosure considers polycarbonates, and

polyanhydrides as equivalents and provides no criticality to the particular above mention polymers. Thus, it would be obvious to on with ordinary skill in the art to use polymer selected from the group consisting of poly~glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone rather than polyanhydrides, as recited in column 10, lines 40-60, as they are considered equivalents and within the scope of the invention.

9. Claims 30, 35-39 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Vacanti et al. in US Patent No. 5,759,830 in view of Wallace et al. in US Patent No. 5,733,329.

Regarding claims 30 and 47, Vacanti et al. disclose that as applied to claims 1 and 12. However, an implant that is a coil where the biocompatible and bioabsorbable polymer that restricts coil compaction by accelerated scar formation is not recited. On the other hand, Wallace et al. teach polymer-coated coils, as stated in column 4, lines 45-55. Thus, it would be obvious to one with ordinary skill in the art to when treating blood vessels with the system of Vacanti employ the teachings of Wallace and coat coils.

Regarding claims 35-39, Vacanti et al. disclose that as applied to claim 1. However, an implant that is a hybrid bioactive coil, that is a composite of a

biocompatible and bioabsorbable polymer and an inert biocompatible coil/platinum coil where the coil has thread of biocompatible and bioabsorbable polymer attached to the inert biocompatible coil have not been recited. On the other hand, Wallace et al. teach a polymer-coated coil of platinum, as recited in column 4. Thus, it would be obvious to one with ordinary skill in the art to when treating blood vessels with the system of Vacanti employ the teachings of Wallace and coat coils.

Allowable Subject Matter

10. Claims 34 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Further, it is recommended to positively recite that the invention is an implantable coil that treats aneurysms.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 5,582,619.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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